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#### REMARKS

Claims 40-47 are pending in the subject application. By this Amendment, applicants have amended claim 40 to indicate the ATCC Accession No. for the deposited PA-6 and PA-7 hybridomas. Applicants note that these amendments are supported by the amendments to the specification described above, and maintain that the amendments to the specification and to claim 40 do not raise any issue of new matter. Accordingly, applicants respectfully request that the Examiner enter this Amendment. Upon entry of this Amendment, claims 40-47, as amended, will be pending and under examination.

Applicants again thank the Examiner for the courtesy extended during the interview held on December 7, 2004, a Summary of which December 7, 2004 prepared by the Examiner on Communication providing a more detailed summary of which was filed by applicants on January 4, 2005. Applicants also thank the Examiner for re-mailing the present March 21, 2005 Office Action after an electronic copy of an Office Action dated December 29, 2004 was posted on the Patent Office's public PAIR site but the actual Office Action was never received by applicants in the mail. Applicants note that in an Interview Summary accompanying the March 21, 2005 Office Action, the Examiner stated that the response period is reset to commence from the mailing date of this Office Action.

## Rejections under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 40-47 under 35 U.S.C. 112, first paragraph, on the ground that the specification allegedly fails to provide an enabling disclosure for the claimed invention. The Examiner stated that it is apparent that the monoclonal antibodies PA-6 and PA-7 are required to practice the claimed invention. The Examiner also stated that as required elements, they must be known

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and readily available to the public or obtainable by a repeatable method set forth in the specification. The Examiner further stated that if they are not so obtainable or available, the enablement requirements of 35 U.S.C. §112, first paragraph, may be satisfied by a deposit of the hybridoma cell line producing said antibodies (citing 37 C.F.R. §1.302).

The Examiner stated that due to the unpredictability associated with antibody production (i.e. each antibody generally has a unique structure) and the failure of the specification to provide any detailed structural information concerning the claimed antibodies, MAbs PA-6 and PA-7 do not appear to be readily available materials. The Examiner further stated that deposit of the hybridoma cell lines producing said antibodies or detailed structural information (i.e. the complete nucleotide or ammo acid sequence of each antibody) would satisfy the enablement requirement of 35 U.S.C. The Examiner also stated that if a deposit is made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty, and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements (citing 37 C.F.R. §1.808).

The Examiner further specified criteria that must be satisfied if the deposits have been made at an acceptable depository but not under the provisions of the Budapest Treaty.

In response, applicants affirm that hybridomas, PA-6 and PA-7, secreting the PA-6 and PA-7 monoclonal antibodies, respectively, were deposited on March 24, 2005, pursuant to the Budapest Treaty, with the Patent Culture Depository of the American Type Culture

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Collection (ATCC) under ATCC Accession Nos. PTA-6637 (PA-6) and PTA-6638 (PA-7), respectively. For the Examiner's convenience, applicants attach hereto as **Exhibit A** a copy of the April 8, 2005 Budapest Treaty Deposit Receipt and Viability Statement for the PA-6 and PA-7 hybridomas. Applicants note also that claim 40 has been amended herein to indicate the ATCC Accession No. for these hybridomas.

In accordance with 37 C.F.R. §1.804(b), applicants attach hereto as **Exhibit B** a Declaration under 37 C.F.R. §1.132 by William C. Olson, Ph.D., Vice President (Research and Development) of Progenics Pharmaceuticals, Inc. to which the subject application is assigned, corroborating that although the original deposit of the PA-6 and PA-7 hybridomas was made after the filing date of the subject application, the biological materials deposited are the same biological materials specifically identified as PA-6 and PA-7 in the application as filed.

Consistent with the requirements of 37 C.F.R. §1.808, and subject to paragraph (b) of §1.808, applicants' undersigned attorney states that the deposit of the PA-6 and PA-7 hybridomas was made under the terms of the Budapest Treaty, and that all restrictions on the availability to the public of the materials deposited under ATCC Nos. PTA-6637 and PTA-6638 will be irrevocably removed upon the granting of a patent from the subject application.

In view of the foregoing, applicants request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §112, first paragraph.

## Amendment of the Specification

The Examiner also stated that the identifying information set forth in 37 C.F.R. §1.809(d) should be added to the specification (referring applicants to 37 C.F R §§ 1.803-1.809 for additional

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explanation of these requirements).

In response, applicants note that the specification has been amended hereinabove in conformance with the Examiner's request. In accordance with 37 C.F.R. §1.809(d), the specification, as amended, provides the ATCC Accession Nos. for the deposits, the date of the deposits, a description of the deposited hybridomas sufficient to specifically identify them and to permit examination, and the name and address of the ATCC depository.

#### Examiner's Response to Applicants' Arguments

The Examiner stated that the arguments made by applicants in their Amendment filed March 29, 2004, and the declaration(s) referenced therein, were carefully considered and were considered to be persuasive as directed toward the rejections set forth in the last Office action.

In response, and in view of the remarks presented hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the claim rejections set forth in the March 21, 2004 Office Action, and allow pending claims 40-47, as amended.

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## Supplemental Information Disclosure Statement

This Supplemental Information Disclosure Statement is submitted under 37 C.F.R. §1.97(c)(2) to supplement the Information Disclosure Statement filed on January 7, 2002 in connection with the subject application.

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following documents which are listed on the attached Form PTO-1449 (Exhibit C), and certain of which are attached hereto as Exhibits 1-18:

- 1. U.S. Patent No. 5,994,515 A, issued November 30, 1999 to J.A. Hoxie;
- 2. U.S. Patent No. 6,107,019 A, issued August 22, 2000 to G.P. Allaway et al.;
- 3. U.S. Patent No. 6,261,763 B1, issued July 17, 2001 to G.P. Allaway et al.;
- 4. U.S. Patent No. 6,344,545 Bl, issued February 5, 2002 to G.P. Allaway et al.;
- 5. U.S. Patent No. 6,759,519 B2 issued July 6, 2004 to Y. Li and S. M. Ruben;
- 6. W.C. Olson et al., U.S. Patent Application Publication No. 2003/0228306 A1, published December 11, 2003;
- 7. W.C. Olson and P.J. Maddon, U.S. Patent Application Publication No. 2004/0228869 A1, published November 18, 2004;
- 8. PCT International Application Publication No. WO 95/16789, published December 16, 1994 (Exhibit 1);

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- 9. PCT International Application Publication No. WO 96/41020, published December 19, 1996 (Exhibit 2);
- 10. PCT International Application Publication No. WO 97/37005,
  published October 9, 1997 (Exhibit 3);
- 11. PCT International Application Publication No. WO 97/45543, published December 4, 1997 (Exhibit 4);
- 12. PCT International Application Publication No. WO 97/47319, published December 18, 1997 (Exhibit 5);
- 13. PCT International Application Publication No. WO 97/49424, published December 31, 1997 (Exhibit 6);
- 14. PCT International Application Publication No. WO 98/56421, published December 17, 1998 (Exhibit 7);
- 15. PCT International Application Publication No. WO 00/35409, published June 22, 2000 (Exhibit 8);
- 16. G.P. Allaway, U.S. Serial No. 08/169,311, filed December 17, 1993 (now abandoned);
- 17. G.P. Allaway, U.S. Serial No. 08/475,515, filed June 7, 1995 (now abandoned) (Exhibit 9);
- G.P. Allaway et al., U.S. Serial No. 08/627,684, filed April
   1996 (now abandoned) (Exhibit 10);
- 19. G.P. Allaway et al., U.S. Provisional Application No.
  60/014,532, filed April 2, 1996;
- 20. G.P. Allaway et al., U.S. Serial No. 08/663,616, filed June

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- 14, 1996 (now abandoned) (Exhibit 11);
- 21. G.P. Allaway et al., U.S. Serial No. 08/673,682, filed June 25, 1996 (now abandoned) (Exhibit 12);
- 22. Allowed claims in G.P. Allaway et al., U.S. Serial No. 09/412,284, filed October 5, 1999 (Exhibit 13);
- 23. Pending claim in G.P. Allaway et al., U.S. Serial No. 09/460,216, filed December 13, 1999 (Exhibit 14);
- 24. Pending claims in G.P. Allaway et al., U.S. Serial No. 09/888,938, filed June 12, 2001, and published October 24, 2002 as U.S. Patent Application Publication No. 2002/0155429 Al (Exhibit 15);
- 25. Pending claims in G.P. Allaway et al., U.S. Serial No. 09/904,356, filed July 12, 2001, and published April 18, 2002 as U.S. Patent Application Publication No. 2002/0045161 Al, (Exhibit 16);
- 26. G.P. Allaway et al., U.S. Serial No. 08/665,090, filed June 14, 1996 (now abandoned) (Exhibit 17); and
- 27. Pending claims in G.P. Allaway et al., U.S. Serial No. 09/724,105, filed November 28, 2000 (Exhibit 18).

The Examiner is respectfully requested to make these documents of record in the present application by initialing and returning a copy of the enclosed Form PTO-1449.

Pursuant to 37 C.F.R. §1.98(a)(2), as amended in the September 21, 2004 Final Rule, copies of the above-cited U.S. Patents and patent application publications (references 1-7) are not attached hereto.

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37 C.F.R. §1.98(a)(2)(iii) provides that an Information Disclosure Statement shall include, for each cited pending U.S. application, a legible copy of the application specification including the claims and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion. Under 37 C.F.R. §1.98(c), when the disclosures of two or more patents or publications listed in an Information Disclosure Statement are substantively cumulative, a copy of one of the patents or publications may be submitted without copies of the other patents or publications, provided it is stated that these other patents or publications are cumulative. In accordance with 37 C.F.R. §1.98(c), copies of certain of the references listed above are not attached hereto as they are cumulative.

Specifically, PCT International Application Publication No. WO 95/16789, published December 16, 1994 (reference 8) claims priority of and is identical to U.S. Serial No. 08/169,311, filed December 17, 1993 (now abandoned) (reference 16). Therefore, references 8 and 16 are cumulative to each other since each contains an identical disclosure. Accordingly, pursuant to 37 C.F.R. \$1.98(c), a copy of reference 16 is not attached hereto.

References 18 and 19 are cumulative to each other since each contains an identical disclosure. Therefore, pursuant to 37 C.F.R. \$1.98(c), a copy of reference 19 is not attached hereto.

U.S. Serial No. 09/412,284, filed October 5, 1999, is a continuation of U.S. Serial No. 08/973,601, filed March 16, 1998, which issued as U.S. Patent No. 6,261,763 B1 (reference 3). Therefore, a copy of U.S. Serial No. 09/412,284 is not attached hereto. However, in accordance with 37 C.F.R. \$1.98(a)(2)(iii), a copy of the claims allowed in U.S. Serial No. 09/412,284 is attached hereto as Exhibit 13.

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U.S. Serial No. 09/460,216, filed December 13, 1999, is a \$371 national stage application of PCT International Application Publication No. WO 98/56421, published December 17, 1998 (reference 14). Therefore, a copy of U.S. Serial No. 09/460,216 is not attached hereto. However, in accordance with 37 C.F.R. \$1.98(a)(2)(iii), a copy of the single claim pending in U.S. Serial No. 09/460,216 is attached hereto as Exhibit 14.

- U.S. Serial No. 09/888,938, filed June 25, 2001 (and published October 24, 2002 as U.S. Patent Application Publication No. 2002/0155429), is a continuation of U.S. Serial No. 10/831,823, filed April 2, 1997, which issued as U.S. Patent No. 6,344,545 B1 (reference 4). Therefore, a copy of U.S. Serial No. 09/888,938 is not attached hereto. However, in accordance with 37 C.F.R. \$1.98(a)(2)(iii), a copy of the claims pending in U.S. Serial No. 09/888,938 is attached hereto as Exhibit 15.
- U.S. Serial No. 09/904,356, filed July 12, 2001 (and published April 18, 2002 as U.S. Patent Application Publication No. 2002/0045161 A1), is a continuation of U.S. Serial No. 08/973,601, filed March 16, 1998, which is a national stage application of PCT International Application Publication No. WO 96/41020, published December 19, 1996 (reference 9). Therefore, a copy of U.S. Serial No. 09/904,356 is not attached hereto. However, in accordance with 37 C.F.R. \$1.98(a)(2)(iii), a copy of the claims pending in U.S. Serial No. 09/904,356 is attached hereto as Exhibit 16.
- U.S. Serial No. 09/724,105, filed November 28, 2000, is a continuation of U.S. Serial No. 08/874,618, filed June 13, 1997, which has the same disclosure as PCT International Application Publication No. WO 97/47319, published December 18, 1997 (reference 12). Therefore, a copy of U.S. Serial No. 09/724,105 is not attached hereto. However, in accordance with 37 C.F.R. \$1.98(a)(2)(iii), a copy of the claims pending in U.S. Serial No. 09/724,105 is attached hereto as Exhibit 18.

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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Pursuant to 37 C.F.R. \$1.97(c)(2) and 1.17(p), a fee of one hundred and eighty dollars (\$180.00) is required for filing the enclosed Supplemental Information Disclosure Statement and a check for this amount is enclosed. No additional fee is deemed necessary in: connection with the filing of this response. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

hereby certify that · correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

John P. White Reg. No. 28,678

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# BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

#### INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.

To: (Name and Address of Depositor or Attorney)

Cooper & Dunham LLP Attn: John P. White, Esq. 1185 Avenue of the Americas New York, NY 10036

Deposited on Behalf of: Progenics Pharmaceuticals, Inc.

Identification Reference by Depositor:

**Patent Deposit Designation** 

Mouse Hybridoma: PA-6 Mouse Hybridoma: PA-7 Docket No: 2048/48965-B PTA-6637 PTA-6638

The deposits were accompanied by: \_\_ a scientific description a proposed taxonomic description indicated above. The deposits were received March 24, 2005 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested March 29, 2005. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Marie Harris, Patent Specialist, ATCC Patent Depository

Date: April 8, 2005

BP4/9